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EXAMINER	
DIETRICH, JOSEPH M	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,349	REZAI ET AL.	
	Examiner	Art Unit	
	Joseph M. Dietrich	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 March 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5 and 7-36* is/are pending in the application.

4a) Of the above claim(s) *37,41 and 42* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5 and 7-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *23 July 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/23/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 16, 2009 has been entered.

Election/Restrictions

2. Applicant's election without traverse of Group I (claims 1 – 5 and 7 – 36) in the reply filed on March 27, 2009 is acknowledged.

Claim 67, 71, and 72 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on March 27, 2009.

Information Disclosure Statement

3. An updated, initialed IDS has been attached indicating that the copy of Rezai et al., "Deep Brain Stimulation for Chronic Pain," in *Surgical Management of Pain*, Chapt. 44, pp. 565-576 (2002) has been received and considered by the Examiner.

Response to Amendment

4. The declaration under 37 CFR 1.132 filed January 16, 2009 is insufficient to overcome the rejection of claims 1 - 36 based upon Baudino under 35 USC 103 as set forth in the last Office action because: it fails to provide sufficient evidence to overcome the prior art as discussed below. Furthermore, new grounds of rejection have been raised, necessitated by amendment, and the affidavit needs to address these new grounds of rejections on the presently pending claims, not on a previous office action based on unamended claims.

Response to Arguments

5. Applicant's arguments filed 6 May 2008 have been fully considered but they are not persuasive.

Regarding the 102(e) rejection by Baudino et al., applicant argues that the Baudino reference merely mentions affecting chronic pain and stimulating certain cites of the brain in passing. Applicant argues that this does not amount to a teaching of affecting chronic pain by stimulating those mentioned sites. Examiner disagrees. As set forth in Baudino, "The features and advantages of the present invention for steering an electric field within a brain, a spinal cord, or a peripheral nerve may be implemented in numerous applications. It is generally desirable to excite particular neural tissue elements of the brain to provide a certain treatment such as treatment of a neurological disorder, the relief of chronic pain or to control movements" (e.g. column 9, lines 18 – 24). As shown, Baudino clearly teaches that the present invention is used to treat

chronic pain.

Furthermore, applicant argues that a passage set forth in Baudino (column 9, lines 24 - 25) states to avoid the internal capsule. Column 9, lines 24 – 30, states, "Often, nearby groups of neurons or axons, e.g. the optic nerve, internal capsule, or medical lemniscus, are in special orientations and groupings. It may be advantageous to avoid affecting them (e.g. preventing stimulation of the perception of the flashes of light) or deliberately to affect them (e.g., excite or inhibit axons of passage)." As shown, Baudino teaches that it may be advantageous to stimulate certain areas for the purposes of the invention described by Baudino.

Applicant also argues that the sites mentioned in Baudino column 9, line 61 to column 10, line 9 are mentioned in conjunction with configuration changes of the device and are certainly not linked to any specific disorders, let alone chronic pain. Applicant does not claim any specific configuration other than 'implanting a stimulator in a target site of the brain.' Baudino states that "the present invention may be used to deliver treatment therapy to any number of sites in the brain." Baudino teaches that the present invention excited particular neural tissue elements of the brain to provide a certain treatment such as relief of chronic pain, and that the invention may be used to deliver treatment therapy to any number of sites in the brain.

Applicant argues that Baudino does not describe detecting a bodily activity associated with chronic pain and providing a stimulation signal in response to the detected bodily activity to stimulate the target site to affect chronic pain. However, in column 2, lines 57 – 62, Baudino teaches sensing the physical condition for treating

pain and using the signal generated by the sensing to adjust at least one parameter of the electrical energy provided to the electrode. Because the sensor generates a signal related to the extent of a physical condition for treating a neurological disorder or pain, it is considered to be a "bodily activity of the body associated with the chronic pain." Because the signal generated by the sensor adjusts at least one parameter of the electrical energy, it "provides a stimulation signal to the stimulator in response to the detected bodily activity."

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 21, 22, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 21, 22, and 33 recite that the target site is the intralaminar thalamic nuclei, the dorsomedial nucleus of the thalamus, or the ventral thalamus. These are limitations that are not included in independent claim 19 as part of the group of selected target sites. Because Claim 19 uses "consisting" language, which limits the group to only target sites that are listed, claims 21, 22, and 33 are unclear and not consistent with the independent claim. It is suggested to cancel these dependent claims or add the limitations found in the dependent claims to the independent claim.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1 – 5 and 7 – 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baudino et al. (U.S. Patent 6,353,762).

Regarding **claims 1 and 4**, Baudino discloses a method of affecting chronic pain in a patient comprising: implanting a stimulator in a target site of the brain (e.g. column 9, lines 61 – 66); detecting a bodily activity of the body associated with chronic pain (e.g. column 2, lines 57 – 60); and providing stimulation to the stimulator in response to the detected bodily activity to stimulate the target site to affect chronic pain (e.g. column 9, lines 18 – 24), wherein the target site is the anterior limb of the internal capsule (e.g. column 9, line 66); but fails to teach that the stimulation signal has the following parameters: a voltage between about 1V to about 15V; a frequency between about 2Hz and 2500 Hz; and a pulse width between about 10 microseconds to about 1,000

microseconds. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation signal as taught by Baudino, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art [*In re Aller*, 105 USPQ 233] and/or since it has been held that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. Titanium Metals Corp. of America v. Banner, 778 F.2d 775, 227 USPQ (Pease see MPEP 2144.05).

In addition, it is well known in the art of brain stimulation to use a voltage between about 1V to about 15V; a frequency between about 2 Hz and 2500 Hz; and a pulse width between about 10 microseconds to about 1,000 microseconds in order to stimulate specific areas of the brain. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation as taught by Baudino, with a voltage between about 1V to about 15V; a frequency between about 2 Hz and 2500 Hz; and a pulse width between about 10 microseconds to about 1,000 microseconds since it was known in the art that stimulation using the claimed parameters is used to provide the predictable results of stimulating specific locations in the brain.

Regarding **claims 19, 20, 22, 24, and 36**, Baudino discloses the target site is selected from the group consisting of the anterior nucleus of the thalamus (e.g. column 9, line 67), the dorsomedial nucleus of the thalamus (e.g. column 9, line 67), the lateral

hypothalamus (e.g. column 10, line 3), and the ventral pallidum (e.g. column 9, line 65).

Regarding **claims 2, 3, 5, 7 - 18, 21, 23, and 25 - 35**, Baudino discloses the claimed invention, but fails to expressly teach that the target area is selected from the groups consisting of: the insular cortex, the secondary somatosensory cortex, the inferior frontal gyrus, the middle frontal gyrus, the superior frontal gyrus, the medical frontal gyrus, the parahippocampal gyrus, the precuneus, the mammillary body, and the tectum. It would have been an obvious matter of design choice to a person of ordinary skill in the art to modify the cortical stimulation and the deep brain stimulation as disclosed by Baudino with the stimulation of the identified cortical or deep brain sites, because Applicant has not disclosed that the stimulation of the claimed sites provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the stimulation of the anterior limb of the internal capsule or the anterior nucleus of the thalamus as taught by Baudino, because it provides the predictable results of effective stimulation to affect chronic pain.

Therefore, it would have been an obvious matter of design choice to modify Lozano to obtain the invention as specified in the claim(s).

In addition, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the cortical and deep brain stimulation methods as taught by Baudino and try different cortical and/or deep brain stimulation sites, such as the stimulation of the claimed sites, since it was known in the art that cortical and deep brain stimulation systems and methods use stimulation of the insular

cortex, the secondary somatosensory cortex, the inferior frontal gyrus, the middle frontal gyrus, the superior frontal gyrus, the medical frontal gyrus, the parahippocampal gyrus, the precuneus, the mammillary body, or the tectum and since it would be obvious to one having ordinary skill in the art to try different cortical or deep brain stimulation sites to provide the predictable results of determining the correct cortical or deep brain region to stimulate to affect chronic pain since different brainstem stimulation sites provide activation of selective nerves and different body regions having different functions and would allow the physician to choose the most effective site to modulate body function.

11. Claims 1 – 5 and 7 – 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baudino et al. in view of Schiff (U.S. Patent 5,938,688).

Regarding **claims 1 – 5 and 7 – 36**, Baudino discloses the claimed invention except for a stimulation signal having the following parameters: a voltage between about 1 V to about 15 V; a frequency between about 2 Hz and 2500 Hz; and a pulse width between about 10 microseconds to about 1,000 microseconds. Schiff teaches it is known to use a stimulation signal having the following parameters: a voltage between about 1 V to about 15 V; a frequency between about 2 Hz and 2500 Hz; and a pulse width between about 10 microseconds to about 1,000 microseconds (e.g. column 5, lines 20 – 24) for treating chronic pain. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the stimulation signal as taught by Baudino with the signal having the claimed parameters as taught by Schiff, since such a modification would provide the predictable results of using optimum

and workable ranges in order to treat a patient suffering from chronic pain.

It is noted that because Schiff discloses that patients with impaired cognitive function accompanied by chronic pain can benefit from the practice of Schiff's invention, Schiff teaches that chronic pain is affected by this method.

Regarding **claims 21, 26 – 31, and 33 – 35**, Baudino discloses the claimed invention, but fails to expressly teach that the target area is selected from the groups consisting of the intralaminar thalamic nuclei, the locus coeruleus, the dorsal raphe nucleus, the substantia nigra pars compacta, the substantia nigra pars reticulate, the superior colliculus, the tegmentum, the medial thalamus, the nucleus accumbens, the ventral striatum. Schiff teaches it is known to affect chronic pain (e.g. column 2, lines 20 – 23 and 43 – 47) by stimulating a target site, wherein the target site is selected from the group consisting of the intralaminar thalamic nuclei (e.g. column 4, lines 58 – 61), locus coeruleus (e.g. column 8, line 20), dorsal raphe nucleus (e.g. column 8, line 20), substantia nigra pars compacta (e.g. columns 9 and 10, Table 1), substantia nigra pars reticulate (e.g. columns 9 and 10, Table 1), superior colliculus (e.g. columns 9 and 10, Table 1), tegmentum (e.g. column 8, line 19), medial thalamus (e.g. column 14, lines 45 – 50), nucleus accumbens (e.g. column 13, lines 5 – 6), ventral striatum (e.g. column 8, line 2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the sites of the brain as taught by Baudino with the claimed sites of the brain as taught by Schiff, since such a modification would provide the predictable results stimulating only the regions that optimize the therapeutic results felt by the patient and avoiding inadvertently stimulating surrounding areas of the brain.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph M. Dietrich whose telephone number is (571)270-1895. The examiner can normally be reached on M-F, 8:00 - 5:00 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571-272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. M. D./
Examiner, Art Unit 3762
5/8/09

/George R Evanisko/
Primary Examiner, Art Unit 3762